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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,784	02/21/2002	Franco Lombardo	PC11861A	2702
23913	7590	12/15/2004	EXAMINER	
PFIZER INC 150 EAST 42ND STREET 5TH FLOOR - STOP 49 NEW YORK, NY 10017-5612			LUDLOW, JAN M	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/081,784

Applicant(s)

LOMBARDO ET AL.

Examiner

Jan M. Ludlow

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/20-11/8/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 20, 2004 has been entered.
2. With respect to the IDS filed October 20, 2004, only one page of reference citations was found in the file, but eleven additional non-patent literature references were scanned into the file and considered. Applicant is requested to supply a copy of the missing Form 1449 page(s) for completeness of the record.
3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
  4. A person shall be entitled to a patent unless –
    5. the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  7. A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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9. Determining the scope and contents of the prior art.
10. Ascertaining the differences between the prior art and the claims at issue.
11. Resolving the level of ordinary skill in the pertinent art.
12. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1, 3, 5-7, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minick et al (J. Chrom 461 (1989) 177-191) in view of Abraham (J. Chromatogr. A 685 (1994) 203-211).

15. Minick teaches correlating log P using a C18 column and the claimed buffer conditions resulting in correlations with constant ranges, which overlap the constant ranges of instant Eq. 1 (see, e.g., p. 180, Eqn (i) of Table II, legend of Figure 4 and Eqn (d) of Table V). Minick fails to teach that log D is determined from the equation for other samples or that the C18 column has "low silanol activity."

16. Abraham teaches that log P can be estimated by analyzing samples in the same system used to determine a correlation and using the correlation to calculate the sample log P (p. 203).

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17. It would have been obvious to one of ordinary skill to chromatograph a sample in the system of Minick and calculate log P from the correlations of Minick in order to determine log P from an HPLC correlation as taught by Abraham. To the extent that "low silanol activity" has been defined, it is the examiner's position that the C18 column has "low" activity in that it is used to determine log P using the claimed solvent system. With respect to claims 5-6, it would have been obvious to use conventional laboratory equipment, such as robotics, to perform the experiments in order to achieve the known advantages of speed and reliability. In that log P is the same as log D at pH values where the compounds are neutral, log P represents log D for neutral compounds at the running pH.
18. Claims 1-4, 6-8 are rejected under 35 U.S.C. 102(a) as being unpatentable over Lombardo et al (July 7, 2000, J. Med Chem v. 43, No. 15, pages 2922-2928).
19. Lombardo teaches correlating log P using an ABZ amide column (see Supelco) and the claimed buffer conditions resulting in correlations with constant ranges which overlap the constant ranges of instant Eq. 1 for use in the instant method (see, e.g., abstract, pp. 2926, 2927 and Eqns. 2, 3). It is the examiner's position that the HPLC 1100 ChemStation is a robotic system under computer control. In that log P is the same as log D at pH values where the compounds are neutral, log P represents log D for neutral compounds at the running pH.
20. Applicant's arguments filed October 20, 2004 have been fully considered but they are not persuasive.

Applicant argues that Minick (J. Chrom 461 (1989) 177-191) is based on the method of Minick (J. Med. Chem 1988), and that the rejection over Minick (1988) has been overcome. The distinction between the references is that in the currently applied reference, the parameters of the equation overlap the parameters of the instantly claimed equation within the stated errors, and the reference therefore teaches at least some of the equations encompassed by the parameters within the stated error limitations. There is therefore no need to provide motivation to optimize.

Applicant argues that neither Minick (1989) nor Abraham (1994) teach determining log D, which is broader than log P. However, applicant admits that for certain compounds, log P "is indeed" log D. The examiner notes that the instant claims are directed to "chemical compounds" broadly and do not require that any of the compounds be those for which log P is not the same as log D, e.g., compounds which are not neutral at pH 7.4 as argued at page 6 of the response. It is suggested that applicant review the specification and amend the claims to reflect that the method is applicable to non-neutral chemical compounds, using language supported by the specification.

Applicant argues that Lombardo does not teach determining log D, which is broader than log P. However, applicant admits that for certain compounds, log P "is indeed" log D. The examiner notes that the instant claims are directed to "chemical compounds" broadly and do not require that any of the compounds be those for which log P is not the same as log D, e.g., compounds which are not neutral at pH 7.4 as argued at page 6 of the response. It is suggested that applicant review the specification

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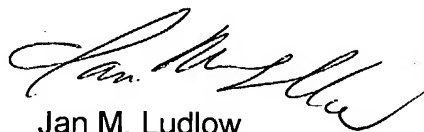
and amend the claims to reflect that the method is applicable to non-neutral chemical compounds, using language supported by the specification.

In summary, both Minick and Lombardo teach specific examples of determining log D, where the "chemical compounds" are neutral and log P equals log D. The specific examples make obvious or anticipate the broader claim directed to "chemical compounds" in general.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jan M. Ludlow  
Primary Examiner  
Art Unit 1743

Jml  
December 13, 2004